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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/600,673 07/20/00 DAGGY

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EXAMINER

HOLLERAN, A

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

10/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/600,673

Applicant(s)

DAGGY ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The preliminary amendment filed January 20, 2000 (Paper No. 3) is acknowledged.

Claims 1-18 are pending and examined on the merits.

Informalities

2. In claims 3 and 12, the word psyllium appears to be misspelled.

Claim Rejections - 35 USC § 112

3. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 10 are indefinite for reciting "cellulose derivative". The scope of the term cellulose derivative is not fully described by the specification, and may read on a compound that comprises only a portion of a cellulose molecule.

Claims 6 and 15 are indefinite because the phrase "the cellulose" lacks antecedent basis.

Claims 8, 9, 17 and 18 are indefinite because the phrase "the total daily dosage" lacks antecedent basis.

4. Claims 1 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The basis for this rejection is that the disclosure of four species of cellulose derivatives is not adequate to describe the full scope of the cellulose derivatives as recited in claims 1 and 10. Because the scope of the term "derivative" includes fragments, fragments that may be as small as one atom of a cellulose molecule, the multitude of structures encompassed by the phrase "cellulose derivative" is large and includes structures of that have little in common structurally. Thus, the disclosure of four species of cellulose derivatives is not representative of the genus of cellulose derivatives encompassed by claims 1 and 10. Thus, the methods of claims 1 and 10 are not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed.

5. Claims 1-3, 5-12 and 14-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods where the combination of fibers includes the addition of wheat bran to cellulose, does not reasonably provide enablement for methods where the combination of fibers lacks wheat bran. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation would be required to practice the full scope of the claimed inventions are: 1) quantity of experimentation necessary; 2) the amount of direction or guidance presented in the specification; 3) the presence

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or absence of working examples; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims. See *Ex parte Forman*, 230 USPQ 546, BPAI, 1986.

Claims 1-3, 5-12 and 14-18 are broadly drawn to methods of administering combinations of fibers to mammals for reducing the incidence of either colon cancer or breast cancer, where the combinations may or may not include wheat bran. The specification provides support for the claimed methods by demonstrating that a combination of methylcellulose and wheat bran fibers have a synergistic effect over the administration of methylcellulose alone or wheat bran alone. The specification fails to provide any support for methods where the combination of fibers would comprise methylcellulose and psyllium, without the addition of wheat bran. Thus, claims 1 and 10, which recite “in combination with an insoluble fiber and/or a soluble fiber”, are not supported to the extent that the combination of fibers may be two soluble fibers (methylcellulose and psyllium).

The prior art appears teaches that combinations of soluble and insoluble fibers are synergistic in the reduction of colon cancer risk and breast cancer risk (see Cohen et al (Cohen, L.A. et al., *J. Natl. Cancer Inst.*, 88(13): 899-907, 1996; cited in the IDS) or Alabaster et al (Alabaster, O. et al. *Cancer Letters* 75: 53-58, 1993; cited in the IDS). There does not appear to be teachings in the prior art that would support methods for combining two soluble fibers.

In view of the breadth of the claims, the support provided by the specification and the teachings of the prior art, it appears that undue experimentation would be required to practice the claimed methods to the extent that they read on administering combinations of two soluble fibers without the addition of an insoluble fiber.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1, 2, 5, 6, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Annison et al (U.S. Patent 5,840,860; issued 11/24/1998; effective filing date for 102(e) 9/5/1996).

Claim 1 is drawn to a method for reducing the incidence of colorectal cancer comprising administering a cellulose derivative. The cellulose derivative may be administered alone. Claim 2 adds the limitation that the cellulose derivative is a cellulose ether which is methylcellulose, ethylcellulose, carboxymethyl cellulose, hydroxypropyl-methylcellulose, or a combination thereof. Claims 5 limits the cellulose derivatives to methylcellulose, and hydroxypropyl-methylcellulose. Claim 6 adds the limitation that the cellulose derivative is administered in the form of bulk powder, a tablet, or suspension, which optionally contains sugar. Claims 8 and 9 limit the dosage to ranges of 0.4 gm/day –30 gm/day, and 1 gm/day to 10 gm/day, respectively.

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Annison teaches a method comprising the administration of a short chain fatty acid covalently bonded to a cellulose (reads on a cellulose derivative). Annison teaches that the method may be used for lowering the risk of a colon disorder such as colonic cancer (see claims 24-26, col. 24). Annison also claims that the cellulose may be in the form of methylcellulose or hydroxypropylmethylcellulose (see claim 31). Annison teaches that the esterified cellulose may be formulated into a powder or tablet form, teaches ranges of dosages that are within the claimed ranges (see column 8, lines 7-17, lines 37-42; column 23, lines 1-3). Thus, Annison teaches and claims methods that are the same as that claimed.

7. Claims 1, 2, 5, 6, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Folino et al (Folino, M. et al, J. Nutr. 125: 1521-1528, 1995).

Folino teaches a method of administering methylcellulose to rats (see page 1522, 1st column, and Table I, page 1523). Folino teaches that the methylcellulose accounted for 1 gm of the total fiber (see Table 1). The methylcellulose appears to be administered in the form of a suspension (see notes of Table 1). Thus, Folino teaches a method that is the same as that claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 10, 11, 14, 15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Annison et al (*supra*) in view of Cohen et al (Cohen, L.A. et al., J. Natl. Cancer Inst., 88(13): 899-907, 1996; cited in the IDS).

Claims 10, 11, 14, 15, 17 and 18 are drawn to methods comprising the same steps as those of claims 1, 2, 5, 6, 8 and 9, but are directed to methods of reducing the incidence of breast cancer. Annison fails to suggest that the methods would be appropriate for preventing breast cancer. However, Cohen teaches that administration of dietary fiber decreases the risk of breast cancer (see abstract). Thus, it would have been *prima facie* obvious to one of skill in the art to use the methods of Annison for the reduction of breast cancer.

9. Claims 10, 11, 14, 15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Folino et al (Folino, M. et al, J. Nutr. 125: 1521-1528, 1995) in view of Cohen et al (*supra*).

Folino fails to suggest a method of administering methylcellulose to rats, where the method would be beneficial for reducing breast cancer. However, Cohen teaches that administration of dietary fiber decreases the risk of breast cancer (see abstract). Thus, it would have been *prima facie* obvious to one of skill in the art to use the methods of Folino for the reduction of breast cancer.

10. Claims 1, 4, 10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Annison et al (*supra*) or Folino et al (*supra*) in view of either Cohen et al (Cohen, L.A. et al., J.

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Natl. Cancer Inst., 88(13): 899-907, 1996; cited in the IDS) or Alabaster et al (Alabaster, O. et al., Cancer Letters, 75: 53-58, 1993; cited in the IDS).

Claims 1, 4, 10 and 13 are interpreted to be drawn to methods of reducing the incidence of either colon cancer or breast cancer comprising administering a soluble cellulose derivative in combination with an insoluble fiber such as wheat bran.

Annison or Folino teach methods of administering cellulose derivatives. Neither teach administering cellulose derivatives in combination with an insoluble fiber such as wheat bran. However, either of Cohen or Alabaster teaches that combinations of soluble and insoluble fibers have a synergistic effect in colon or breast cancer risk reduction (see abstracts). Thus, it would have been prima facie obvious to one of skill in the art at the time the invention was made to have combined a soluble cellulose derivative with wheat bran to make the claimed inventions.


Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.


Anne L. Holleran
Patent Examiner
September 30, 2001


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